



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,183	06/19/2001	Robert W. Blakesley	0942.4150002	1167

26111 7590 12/18/2002

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W., SUITE 600
WASHINGTON, DC 20005-3934

EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
----------	--------------

1637

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant(s)	Applicant(s)	
	09/883,183	BLAKESLEY, ROBERT W.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 52-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 52-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

This Office Action responds the Amendment received on October 2, 2002 (Paper No. 6).

Preliminary Remark

The Examiner of record has been changed. All further correspondence regarding this application should be directed to Examiner Young J. Kim whose Group Art Unit is 1637.

The IDS received on February 7, 2002 (Paper No. 3) and the references listed in the corresponding PTO-1449 have been considered and the signed copy is enclosed herein.

Double Patenting

The statutory double patenting rejection of claim 1 under 35 U.S.C. 101, [*as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,291,164, issued on September 18, 2001*], in the Office Action mailed on May 16, 2002, is withdrawn in view of the Amendment received on October 2, 2002.

Rejections, New Grounds: Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 79-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 79 is indefinite for the recitation of improper Markush group (for the group of enzymes), because the claim is missing a conjunction rendering the claims indefinite in what the group includes. Amending the claim to recite, "...an enzyme selected from the group consisting of ... a nucleotidyltransferase, **and** a carboxylase; a substrate which is capable of either..." would overcome this rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 52-84 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 and 36-51 of U.S. Patent No. 6,291,164. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons illustrated below.

Claims 1 and 52-64 and 84 are drawn to a method of synthesizing nucleic acids via use of various enzymes. Claims 65-78 are drawn to a composition for conducting the method claims. Claims 79-83 are drawn to a kit for use in the method claims.

I) Method Claims:

Claim 1 of the instant application is different in wording from claims 1 and 2 of the '164 patent. The dependent claims of the instant application, specifically, claims 52-64 and 84 are identical in scope to claims 3-13 of the '164 patent with the exception of claims 60, 61, 62, and 84 drawn to an obvious modification discussed below.

Claim 1 is drawn to a method of making at least one nucleic acid molecule wherein the steps involved are same as the steps described in claims 1 and 2 of the '164 patent with the exception of optionally including a reverse transcriptase. Although the claims are not identical in their scope due to this optional ingredient, the claims are obvious in view of the fact that the inclusion of a reverse transcriptase in the method steps is an optional step (*i.e.*, "or at least on reverse transcriptase"). Further, claim 1 of the instant application is also drawn to a method of making more than one first nucleic acid synthesized from a template nucleic acid. However, such modification is an obvious modification in view of the knowledge of an artisan in the field of amplification (*i.e.*, PCR, linear amplification, etc) (see MPEP 2144.03) as well as demonstrated by other method claims of the '164 patent wherein the claims explicitly recite making one or more copies of the template (see claim 14 of the '164 patent).

Furthermore, even if, *arguendo*, the reverse transcriptase was a required (therefore not optional) ingredient in the presently claimed method claims, such modification is still determined to be an obvious modification of the method claim of the '164 patent because patent specification, on column 9 lists all the polymerases that would work with the patented method, including a reverse transcriptase and an AMV reverse transcriptase.

Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in modifying the patented method to include a reverse transcriptase as an optional (or mandatory) enzyme.

II) Composition and Kit Claims:

Claims 65-78 of the instant application is drawn to a composition to be used in the method claims. Claims 36-47 are drawn to a solution comprising the same ingredients with the exception of the reverse transcriptase as an optional enzyme. The obviousness of the optional (or mandatory) inclusion of the reverse transcriptase has been discussed *ut supra* and will not be discussed here. Although claim 65 of the instant application is drawn to a composition while the claim 36 of the '164 patent is drawn to a solution, such claim language does not render it unobvious. All of the ingredients of the composition claims are included in the solution claims of the '164 patent. Although the independent claim 65 of the instant application does not recite "a substrate which is capable of either accepting either a phosphate radical to give a phosphorylated product from pyrophosphate or effecting transfer of pyrophosphate when in the presence of said enzyme," as recited in the independent claim 36 of the patent, such limitation is claimed (verbatim) in claim 74, rendering the claims an obvious modification.

Finally, claims 79-83 of the instant application differs from claims 48-51 in the '164 patent in that the patented claims recite container means which comprise the enzymes and other ingredients. However, recitation of the term "container" does not render the claims unobvious because the term does not give any secondary distinguishing characteristics to the kit itself, other than for packaging purposes. All of the ingredients recited in the instantly claimed kit are recited

in the patented kit claims with the exception of optional inclusion of a reverse transcriptase.

Such modification, as discussed above, is determined to be an obvious modification.

Applicants are advised to file a terminal disclaimer in order to expedite prosecution of these claims.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If

Application/Control Number: 09/883,183


Page 7

Art Unit: 1637

applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

12/12/02



KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

12/16/02